

REMARKS

Status of the claims

Claims 1-13 are currently pending in the present application. The Office Action is non-final. Claims 1-8 and 10-12 are withdrawn from consideration. Claims 9 and 13 remain pending in the present application. Claim 9 has been amended. All amendments are made without prejudice or disclaimer. No new matter has been added by way of the present amendment. Specifically, support for the amendment to Claim 9 where an inadvertent typographical error (maker was corrected to marker) was corrected is located in the specification at page 6, paragraph 1, and page 15, paragraph 3. Additionally, the other amendment to Claim 9 is supported by the specification at page 7, fifth full paragraph.

Issues regarding Objections within the Specification

The Abstract of the Invention is objected to because it is written in the format of a claim. Applicants amended the Abstract to place it in the proper format. Applicants respectfully request reconsideration and withdrawal of the objection.

Applicants respectfully request reconsideration of each of the pending claims (i.e., Claims 9 and 13), based on the following comments.

Issues Under 35 U.S.C. § 112, Second Paragraph

Indefiniteness

Claims 9 and 13 stand rejected under 35 U.S.C. § 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter, which the Applicants regard as the invention. (See Office Action dated March 9, 2007, at page 4). Applicants respectfully traverse the rejection as set forth herein.

The Examiner asserts that the limitation “at position 627 of a wild-type rice acetolactate synthase” in Claim 9 is a relative term which renders the claim indefinite. Since such a position is relative, a recitation of to what the position is relative to is required. Since plants, including rice, which encompasses multiple plant species, can have multiple genes encoding acetolactate synthase, the metes and bounds of the claim are unclear. Claim 13 is also indefinite for the same reason. Thus, the Examiner asserts that the claims do not particularly point out and distinctly claim the subject matter, which the Applicants regard as the invention. Applicants respectfully traverse.

Although Applicants do not agree that the phrase in Claim 9 described above is indefinite, to expedite prosecution, Claim 9 has been amended herein, without prejudice or disclaimer, to recite, in part, “wherein the acetolactate synthase has an amino acid sequence in which a serine corresponding to serine at position 627 of a amino acid sequence of SEQ ID NO: 1 is replaced by isoleucine.” Thus, at least as amended, Claim 9 is directed to a specific amino acid substitution from serine to isoleucine at position 627 of SEQ ID NO: 1. All

amendments and are made without prejudice or disclaimer. Therefore, in light of the amendment of Claim 9, reconsideration and withdrawal of the rejection of Claims 9 and 13 are respectfully requested.

Issues Under 35 U.S.C. § 102(b)/103(a)

Claims 9 and 13 stand rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over WO 01/85970 A2 (published 15 November 2001, hereinafter "Croughan") taken with the evidence of Shimizu et al (NCBI Accession BAB20813, 14 April 2001, hereinafter "Shimizu et al."). Applicants respectfully traverse this rejection, and request reconsideration and withdrawal thereof.

35 U.S.C. § 102(b) - Anticipation

The Examiner asserts that the Croughan reference teaches a gene coding for an ALS in which a serine at position 627 of a wild-type rice ALS is replaced by isoleucine (S627I) and also teaches other substitutions of an ALS at the serine at position 627. Applicants respectfully traverse.

Croughan merely discloses a gene coding for ALS in which a serine at position 627 of wild type rice ALS is replaced by isoleucine at SEQ ID NOs: 4 and 5 (S627I mutant ALS). However, Croughan has never demonstrated the characteristic of the S627I mutant ALS, i.e. herbicide tolerance of the S627I mutant ALS. The disclosed sequence within the Croughan reference was *reported* as a sequence that is herbicide resistant, although the nature of the

herbicide resistance was not specified in the BLAST description (Croughan page 7, lines 22-24).

Additionally, as the Examiner points out, Croughan does not specifically teach the claimed method using a gene coding for an ALS in which a serine corresponding to serine at position 627 of a wild-type rice ALS is substituted with isoleucine. In fact Croughan recites at claim 38 “wherein the encoded AHAS does not have an isoleucine residue at amino acid position 627.”

In contrast, the present inventor clearly shows that the S627I mutant ALS has a very unique herbicide tolerance (See Example 11). Therefore, the Applicants consider that the method according to Claim 9 can provide unexpected results such that the plant having the S627I mutant ALS can be cultivated in the presence of bispyribac-sodium herbicide, pyriithiobac-sodium herbicide, and/or pyriminobac herbicide.

Additionally, as the Examiner points out, Croughan does not specifically teach the claimed method using a gene coding for an ALS in which a serine corresponding to serine at position 627 of a wild-type rice ALS is substituted with isoleucine, in fact Croughan recites at claim 38 “wherein the encoded AHAS does not have an isoleucine residue at amino acid position 627”. The Croughan reference cannot anticipate the present claims because the cited reference fails to disclose all instantly claimed features. *See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Cir. 1986) (“for prior art to anticipate under §102 it has to meet every element of the claimed invention”), *cert. denied*, 480 U.S. 947, 107 S. Ct. 1606 (1987).

In light of this, Applicants respectfully request that the Examiner withdrawal his rejection based upon 35 U.S.C. § 102(b) since Croughan does not disclose all the limitations of the present invention and therefore, Croughan cannot anticipate the present claims.

35 U.S.C. § 103(a)-Obviousness

In the alternative, the Examiner asserts that the instant claims would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicants' invention. Again, Applicants respectfully traverse.

Combination of the Cited References

A proper obviousness inquiry requires consideration of three factors: (1) the prior art reference (or references when combined) must teach or suggest all the claim limitations; (2) whether or not the prior art would have taught, motivated, or suggested to those of ordinary skill in the art that they should make the claimed invention (or practice the invention in case of a claimed method or process); and (3) whether the prior art establishes that in making the claimed invention (or practicing the invention in case of a claimed method or process), there would have been a reasonable expectation of success. *See* M.P.E.P. § 2143.

The teaching, suggestion, motivation test is a valid test for obviousness, but one which cannot be too rigidly applied. *See KSR International Co. v Teleflex Inc.*, 82 USPQ2d 1385, 1395 (U.S. 2007). While the courts have adopted a more flexible teaching/suggestion/motivation (TSM) test in connection with the obviousness standard based on the *KSR v. Teleflex* case which involved a mechanical device in a relatively predictable technological area, it remains true that, despite this altered standard, the courts recognize inventors face additional barriers in relatively unpredictable technological areas as noted in *Takeda Chemical Industries, Ltd. v. Alphapharm*

Pty., Ltd., 83 USPQ2d 1169 (Fed. Cir. 2007) (since TSM test can provide helpful insight if it is not applied as rigid and mandatory formula, and since, in cases involving new chemical compounds, it remains necessary to identify some reason that would have led chemist to modify known compound, in particular manner, in order to establish *prima facie* obviousness of new compound).

“In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification.” *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972). Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. “The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.” *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). See also *In re Lee*, 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (discussing the importance of relying on objective evidence and making specific factual findings with respect to the motivation to combine references); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

A *prima facie* case of obviousness has not been established for this case since Croughan does not anticipate the present claims (as described above) and that Croughan teaches away from the amino acid substitution serine to isoleucine at position 627 of the wild-type rice ALS.

As mentioned above, Croughan merely discloses a gene coding for ALS in which a serine at position 627 of wild type rice ALS is replaced by isoleucine at SEQ ID NOs: 4 and 5 (S627I mutant ALS). However, Croughan has never demonstrated the characteristic of the S627I mutant ALS, i.e. herbicide tolerance of the S627I mutant ALS.

Any cited reference used for a rejection under 35 U.S.C. § 103(a) must be considered in its entirety, i.e., as a whole, including those portions that would lead away from a claimed invention. See *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 220 U.S.P.Q. 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). In other words, the Croughan reference must be read in its entirety, including the teaching away of a point substitution at position 627 with asparagine for herbicide tolerance and avoiding isoleucine at position 627 (see claim 38 Croughan - "does not have an isoleucine residue at amino acid position 627"). Taken the reference as a whole, it may indicate that isoleucine at position 627 may have disadvantages when employed in wild type ALS.

A reference which leads one of ordinary skill in the art away from the claimed invention cannot render it unpatentably obvious. (See, *Dow Chem. Co. v. American Cyanamid Co.* 816 F2d 617, (CAFC 1987)). In determining the scope and content of the prior art, and determining whether the prior art suggested the claimed invention, the references "must be read as a whole and consideration must be given where the references diverge and teach away from the claimed

invention." (*See, Akzo N.V. v. United States Int'l Trade Comm'n*, 1 U.S.P.Q.2d 1241, 1246 (Fed. Cir. 1986); *In re Fine*, 5 U.S.P.Q.2d 1596, 1598-99 (Fed. Cir. 1988)).

The Shimizu et al. reference merely discloses a sequence. Croughan reports this sequence but with the caveat that "the nature of the herbicide resistance was not specified in the BLAST description (Croughan page 7, lines 22-24). Additionally, as the Examiner points out, Croughan does not specifically teach the claimed method using a gene coding for an ALS in which a serine corresponding to serine at position 627 of a wild-type rice ALS is substituted with isoleucine, in fact Croughan recites at claim 38 "wherein the encoded AHAS does not have an isoleucine residue at amino acid position 627."

In light of this information as well as the discussion above, the present invention is non-obvious. It is also non-obvious to use the specific mutation to screen for potential herbicidal resistant plants.

The Croughan reference teaches away from point substitution of the claimed invention. The Croughan reference, taken in its entirety, would teach away from the isoleucine substitution at position 627, since Croughan discussed a different amino acid (asparagine) substitution and avoided isoleucine in claim 38.

Therefore, in light of the amendment of Claim 9, and all the arguments cited above, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 9 and 13.

Non-Statutory Double Patenting

In regards to the issue of obviousness-type double patenting over U.S. Patent No. 7,119,256, Applicants respectfully request reconsideration of the rejection in view of the instantly amended claims. In this respect, it is submitted that the instant claims 9 and 13 (as currently amended) are *patentably distinct* over the claims of U.S. Patent No. 7,119,256. Any contentions to the contrary are respectfully requested to be reconsidered at present.

Additional Matters/Considerations

For the Examiner's consideration it is noted that U.S. Patent No. 7,119,256 to Shimizu et al. issued on October 10, 2006 from PCT/JP01/10014 filed November 16, 2001. The Shimizu et al. patent originally publishes as PCT publication (WO 02/44385) on June 6, 2002. This date is after the priority date of Japanese Application JP 2002-95721 (filed on March 29, 2002) upon which the instant Application ultimately claims priority.

Enclosed herewith is a certified English translation of the JP 2002-95721 priority application. The same provides full 35 USC § 112 support for the invention as instantly claimed.

Accordingly, based on the filing herewith of the certified English translation of JP 2002-95721, it is submitted that the Inventors have perfected their right to priority thereto, and have effectively antedated the same (and U.S. Patent No. 7,119,256 to Shimizu et al.) for all that it

teaches, so that the same is not applicable as cited prior art against the instantly pending claims under the provisions of 35 USC §§ 102 or 103.

Comments Regarding Information Disclosure Statement

Applicants on even date are submitting an Information Disclosure Statement containing PCT Publication WO 02/44385 for consideration of the Examiner.

CONCLUSION

In view of the above amendment and comments, Applicants respectfully submit that the claims are in condition for allowance. A notice to such effect is earnestly solicited.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Paul D. Pyla, Reg. No. 59,228, at the telephone number of the undersigned below, to conduct an interview in an effort to expedite prosecution in connection with the present application.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.14; particularly, extension of time fees.

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Respectfully submitted,

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Attachment- English Translation of Priority Document JP 2002-95721